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Proposed Rule for Importation of Live Swine, Swine Semen, and Pork and Pork Products from Certain Regions Within the European Union

**Environmental Assessment,
March 2003**

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I. Need for Proposed Action

International trade agreements permit countries to place restrictions on trade only if they are scientifically based and transparent. New information indicates that certain regions within the European Union (EU) — Austria, Belgium, certain parts of Germany, Greece, certain parts of Italy, The Netherlands, and Portugal — are now considered to be free of hog cholera (classical swine fever). If this is the case, U.S. regulations governing the import of live swine, swine semen, and pork and pork products from those areas should be revised to reflect the reduced risk of introducing classical swine fever into the United States.

II. Alternatives and Their Impacts

The two alternatives examined include the no action alternative and amending the regulations at 9 Code of Federal Regulations (CFR) 94.9 and 94.10 to allow the importation of live swine, swine semen, and pork and pork products from certain regions of the EU under certain conditions. The conditions pertaining to the importation of pork and pork products and live swine would be added to the regulations in a new section, 9 CFR 94.22. The conditions pertaining to the importation of swine semen would be added to the regulations in a new section, 9 CFR 98.38.

A. No Action Alternative

The no action alternative involves retaining the current importation regulations that do not allow importation of live swine, swine semen, and pork and pork products from the EU regions specified herein (9 CFR 94.9 and 94.10). The no action alternative was not deemed acceptable because the current importation regulations are not supported by data on the status of classical swine fever for the regions in question. Maintenance of such unsupported rules would be contrary to U.S. obligations under international trade agreements.

B. Rule Amendment Alternative

The preferred alternative would allow importation of live swine, swine semen, and pork and pork products from Austria, Belgium, Germany (with the exception of Kreise Uckermark in the Land of Brandenburg; the Kreis Oldenburg, the Kreis Soltau-Fallingbomstel, and the Kreis Vechta in the Land of Lower Saxony; the Kreis Heinsberg and the Kreis Warendorf in the Land

of Northrhine-Westphalia; the Kreis Bernkastel-Wittlich, the Kreis Bitburg-Prüm, the Kreis Donnersbergkreis, the Kreis Rhein-Hunsrück, the Kreis Südliche Weinstrasse, and the Kreis Trier-Saarburg in the Land of Rhineland Palatinate; and the Kreis Altmarkkreis in the land of Saxony-Anhalt), Greece, Italy (with the exception of Emilia-Romagna, Piemonte, and Sardegna), The Netherlands, and Portugal if a certain set of conditions is satisfied. For the importation of live swine, the swine must be breeding swine. The conditions that apply both to live swine to be imported and donor boars are that the live swine and donor boars must (1) meet all import requirements in the regulations and be accompanied by a certificate confirming that the swine or donor boars have never lived in a region listed at that time as a region in which classical swine fever is known to exist, (2) have never transited such a region unless moved directly through such a region in a sealed means of conveyance with the seal determined to be intact upon arrival at the point of destination, and (3) have never been commingled with swine that have been in a region listed at that time as one in which classical swine fever is known to exist. In addition, no equipment or materials used in transporting the swine or donor boars may have been used for transporting animals ineligible for export to the United States under the rule, unless they have been cleaned and disinfected following such previous use. This requirement also applies to movement of donor boars from the farm of origin to the semen collection center, and to the movement of other swine from the farm of origin to the point of entry into the United States.

Also, for the importation of swine semen, the semen may only come from a semen collection center approved for export by the official veterinary services of the national government of the EU Member State in which the collection center is located. And, the donor boar must be held in isolation for at least 30 days prior to entering the collection center and, no more than 30 days prior to being held in isolation, be tested with negative results with a test approved by the International Office of Epizootics.

Further, the donor boar must be observed by the semen collection center veterinarian while the donor boar is at the collection center, including at least a 40-day holding period at the semen collection center following collection of the semen, and, along with all other swine at the center, must exhibit no clinical signs of classical swine fever.

Pork or pork products may be imported into the United States from the EU regions described above provided that the pork or pork products meet all other applicable import requirements in the regulations and provided that they are accompanied by a certificate of origin certifying the following: (1) the articles have not been commingled with pork or pork products produced

from swine from regions in which classical swine fever is known to exist, and (2) the swine from which the pork or pork products were produced have not lived in a region listed at that time as one in which classical swine fever is known to exist and have not transited such a region unless moved directly through such a region in a sealed means of conveyance with the seal determined to be intact upon arrival at the point of destination.

C. Alternatives Eliminated From Further Consideration

Alternatives with requirements differing from those in section II.B. (above) were eliminated from consideration because changes in the requirements would either decrease biosafety or place excessive restrictions on imports that would serve as a *de facto* trade barrier. The certification requirements in the rule provide sufficient biosafety without being overly restrictive.

III. Environmental Impacts of the Action and Its Alternative

A. No Action Alternative

The no action alternative would not allow live swine, swine semen, and pork and pork products to be imported from certain regions of the EU specified herein, *i.e.*, it would maintain the current rules governing the importation of the animals or animal products in question. This alternative would have no effect on human health or the environment. This alternative, however, is inconsistent with the requirements of international trade agreements (North American Free Trade Agreement, 1995, and World Trade Organization, 1995).

B. Rule Amendment Alternative

1. Potential for Spread of Classical Swine Fever

Classical swine fever is a highly contagious viral disease affecting only swine. There are several strains of classical swine fever with variable virulence and antigenicity. The most virulent type produces clinical disease in pigs of all ages and may result in up to 100 percent mortality. Clinical indications of infection by less virulent strains are less severe, and some infected individuals may show no clinical signs. In such cases, the disease may be passed from sow to immunotolerant piglets, thus contributing to the perpetuation of the

disease. Classical swine fever is transmitted by direct contact, through ingestion, and by aerosols. Indirect contact with body secretions and excretions from infected animals and viral contaminations of objects may lead to mechanical transfer of the virus. However, classical swine fever virus strains are host specific (Fraser and Mays, 1986) and the pig is the only natural host (Leman *et al.*, 1992). Classical swine fever, therefore, is not a public health issue because it is not contagious to humans (Fraser and Mays, 1986).

If classical swine fever were to be introduced to the United States as a result of this amendment, it would most likely come from an incursion, *i.e.*, importation into the United States of a single infected animal, swine semen shipment, or box of infected pork discarded by restaurants and institutions and fed to swine. If classical swine fever were diagnosed in the United States, disease eradication would be accomplished by swine depopulation in areas where an effective barrier to the introduction of the disease can be established or through a vaccination program in areas where barriers cannot be used.

2. Preventive Measures

Based on its evaluation of information submitted by the European Commission's (EC's) Directorate General for Agriculture and site visits and meetings with veterinary officials in Belgium, Germany, Spain, and The Netherlands, APHIS' Veterinary Services (VS) has determined that the veterinary infrastructure and regulations, movement controls, disease status and epidemiology in the regions and adjacent regions, disease control programs, control of animal and product movement, livestock demographics and marketing practices, and disease surveillance in the context of disease epidemiology in the EU regions in question support the subject rule. Relevant EU regulations for live animals require veterinary certifications for transport of animals and define procedures for management of outbreaks (including a stamping-out policy), plans to address spread from wild boars, and quarantine and testing requirements for breeding swine and swine semen donors. These regulations are designed to control classical swine fever transmission within and between EU Member States. These regulations are harmonized and binding on all Member States and are believed by VS to be sufficient to ensure the export of classical swine fever-free live swine, swine products, pork, and pork products, provided that there is compliance with the requirements detailed in section II.B.

3. Summary of Environmental Impacts

VS completed a quantitative risk assessment to determine the risk of introducing classical swine fever from live swine, swine semen, and pork and pork products imported from the specified EU regions (USDA, 2000), which is hereby incorporated by reference. The resulting risk estimates incorporate the risk mitigation requirements outlined in section II.B. The risk estimate for introducing classical swine fever from imported breeding swine is one or more incursions in an average of 33,670 years. The risk estimate for introducing classical swine fever by swine semen is one or more incursions in an average of 8,090 years. The risk estimate for introducing classical swine fever in fresh or frozen pork is one or more incursions in an average of 22,676 years. Based on the information available, live swine, swine semen, and pork and pork products imported from certain regions of the EU, consistent with the set of requirements outlined in section II.B., will have a negligible risk of containing the classical swine fever disease agent.

IV. Special Considerations

A. Environmental Justice/Native American Issues

This EA is consistent with Executive Order No. 12898, “Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations.” This action will not result in disproportionately high and adverse human health or environmental effects on any minority populations and/or low-income populations in the United States.

B. Children’s Health Issues

Executive Order 13045, Protection of Children From Environmental Health Risks and Safety Risks (62 FR 19885–19888), and APHIS’ corresponding Directive 5600.3 (USDA, APHIS, 1999) do not apply to this proposed action. The proposed action presents no risks to the health or safety of children.

V. Conclusions

The risk of introducing classical swine fever into the United States as a result of this rule change is negligible. Therefore, the importation of live swine,

swine semen, and pork and pork products from the EU regions specified herein, consistent with the conditions specified in section II.B., should not have any significant adverse impacts on the environment.

VI. Listing of Agencies and Persons Consulted

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VII. References

Fraser, C.M., and Mays, A., 1986. The Merck Veterinary Manual, 7th edition. Merck & Co., Rahway, NJ. 1832 pp.

Leman, A.D., Straw, B.E., Mengeling, W.L., D'Allaire, S., and Taylor, D.J. (Eds.), 1992. Diseases of Swine, 7th edition. Iowa State University Press, Ames. 1021 pp.

USDA, 2000. (United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services.) Risk analysis for importation of classical swine fever virus in swine and swine products from the European Union. 112 pp.

USDA, APHIS, 1999. (U.S. Department of Agriculture, Animal and Plant Health Inspection Service.) Evaluating APHIS Programs and Activities for Ensuring Protection of Children From Environmental Health Risks and Safety Risks. APHIS Directive 5600.3. September 3, 1999.

**Finding of No Significant Impact
for
Final Rule For Importation of Live Swine, Swine Semen, and Pork and Pork Products From
Certain Regions Within the European Union
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The U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services prepared an environmental assessment (EA) that analyzes the potential effects on the human environment of amending the regulations covering the importation of live swine, swine semen, and pork and pork products to recognize certain regions within the European Union (EU) as free of classical swine fever (hog cholera). This amendment would allow live swine, swine semen, and pork and pork products to be imported from the following regions within the EU: Austria, Belgium, The Netherlands, Portugal, and Germany (with the exception of Kreise Uckermark in the Land of Brandenburg; the Kreis Oldenburg, the Kreis Soltau-Fallingb., and the Kreis Vechta in the Land of Lower Saxony; the Kreis Heinsberg and the Kreis Warendorf in the Land of Northrhine-Westphalia; the Kreis Bernkastel-Wittlich, the Kreis Bitburg-Prüm, the Kreis Donnersbergkreis, the Kreis Rhein-Hunsrück, the Kreis Südliche Weinstraße, and the Kreis Trier-Saarburg in the Land of Rhineland Palatinate; and the Kreis Altmarkkreis in the land of Saxony-Anhalt).

The EA was prepared to comply with the National Environmental Policy Act of 1969 (NEPA), as amended (42 United States Code 4321 et seq.), the Council on Environmental Quality regulations for implementing the procedural provisions of NEPA (40 Code of Federal Regulations (CFR) 1500–1508), the USDA regulations implementing NEPA (7 CFR part 1), and APHIS' NEPA Implementing Procedures (7 CFR part 372). The EA is available through the Internet at <http://www.aphis.usda.gov/ppd/es/vsdocs.html> and from the following office:

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The EA analyzed the alternatives of (1) No Action, and (2) Proposed Action. Based on the information presented in the EA, I have selected Alternative 2, Proposed Action, as the preferred alternative because the Final Rule will have no significant impact on the human environment. The import restrictions that will be lifted as a result of this rule are no longer necessary based on the disease status in the specified regions of the EU, and maintaining such unsupported rules would be contrary to U.S. obligations under international trade agreements. The subject rule will not result in disproportionately high and adverse human health or environmental effects on any minority populations and low-income populations, and will not present any risks to the health or safety of children.

/s/

Ron DeHaven
Deputy Administrator
Veterinary Services

3/29/03

Date